UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,783	12/08/2005	Mitsuko Kosaka	64614(70904)	1080

21874 7590 02/09/2009

EDWARDS ANGELL PALMER & DODGE LLP
P.O. BOX 55874
BOSTON, MA 02205

EXAMINER	
DUTT, ADITI	

ART UNIT	PAPER NUMBER
1649	

MAIL DATE	DELIVERY MODE
02/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/559,783	KOSAKA, MITSUKO	
	Examiner	Art Unit	
	Aditi Dutt	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6,8-14,17,18,26 and 27* is/are pending in the application.

4a) Of the above claim(s) *12-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6,8-11,17,18,26 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/4/08,9/25/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 19 November 2008 has been entered.

Status of Claims

2. The amendment filed on 19 November 2008 has been entered into the record and have been fully considered. Claim 1 is amended.

3. Claims 1-4, 6, 8-11, 17-18 and 26-27, drawn to a method for producing tissue cells, that are myocardial cells, comprising culturing iris pigment epithelial cells and obtaining pluripotent cells therefrom, are being considered in the instant application.

Information Disclosure Statement

4, The Information Disclosure Statement dated 9/25/08 has been crossed off because it is identical to the IDS dated 9/4/08.

Response to Amendment

Withdrawn objections and/or rejections

5. Upon consideration of the Applicant's amendment, all claim objections and rejections not reiterated herein have been withdrawn, as overcome by cancellation and/or amendment of claims (19 November 2008).

6. Rejection of claims under 35 U.S.C. 103(a), is withdrawn because of amendment of the claims and Applicant's persuasive arguments.

New grounds of objection/rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-4 and 17-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim fails to identify the metes and bounds of the related subject matter and how that could be ascertained in the stated invention.

8. Claim 1 is rejected for being vague and unclear for not reciting what conditions are encompassed in "differentiation inducing conditions". This rejection can be overcome by reciting specific culture conditions to induce

differentiation, e.g. culture medium, growth factors, other factors and concentration thereof, length of incubation, etc. in the independent claim.

9. Claims 2-4, and 17-18 are rejected as being dependent from a rejected claim.

Claim Rejections - 35 USC § 112-Scope of Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1-4, 6, 17-18 and 26-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for producing myocardial cells comprising isolation of iris pigmented epithelial cells (IPE) and performing adherent culturing of the IPE with DMEM/F12, DMEM or EMEM, comprising FGF, EGF or CNTF and serum, for differentiation of IPE to myocardial cells, does not reasonably provide enablement for a method of generating myocardial cells from IPE using any differentiation inducing condition. The specification is not enabled as broadly claimed, because the culture medium and other essential factors required for inducing directed differentiation of IPE to myocardial cells is not recited in the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

11. The claims are drawn to a method for producing myocardial tissue cells comprising: (i) obtaining iris pigment epithelial cells and dissociating the isolated cells; (ii) culturing epithelial cells by floated coagulated mass in serum free media with N2 supplement and obtaining pluripotent stem cells (claim 1-3); (iii) wherein the stem cells are Oct-3/4 positive (claim 4); (iv) culturing the cells in avian or fetal calf serum containing media, wherein the medium contains a growth factor (e.g. FGF, EGF, etc.) (claims 8-11). The claims further recite the extirpation of iris tissue by excising the tissue from the eyeball of an animal, treating with enzyme (dispase and EDTA) and restoring the tissue in medium containing fetal calf serum (claim 6, 26-27). Furthermore, the claims recite a method comprising testing for a myocardial cell specific gene (claims 17, 18).

12. The factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and, (8) the breadth of the claims. *In re Wands,* 8 USPQ2d, 1400 (CAFC 1988).

13. The specification of the instant application teaches that the iris pigment epithelial cells are obtained from the eyeball of a chick, followed by selective culturing of the cells using the (neurosphere) method of floated coagulated mass culture in a serum-free culture medium (DMEM/F12, N2 supplement and growth

factors FGF2, LIF or SCF) (Example1, pages 18-20). The specification further teaches the differentiation of the iris derived cells under various differentiation inducing culture conditions, and suggests, that the cells can differentiate into all types of tridermic tissues (Example 2, page 21, para 2). The specification generically defines “culturing under the differentiation inducing condition” as “culturing under any publicly known conventional condition designed to differentiate cells", such as culturing using a medium (e.g. DMEM, DMEM/F12) to which serum (e.g. fetal calf serum or avian serum) and growth factor (e.g. FGF, EGF) are added, thereby inducing differentiation to cells (page 5, para 2; Example 1, pages 18-20). Example 2 of the instant specification teaches that stem cells cultured for two months in DMEM comprising specific concentrations of EGF, FGF2, fetal calf serum and avian serum (page 20, para 1, condition 3) resulted in the expression of genes specific for myocardial cells, such as GATA4, Nkx2.5, myosin, etc. (Example 2, pages 20-22; Figure 4). However, the specification does not teach any methods or working examples to indicate that all possible differentiation inducing conditions, meaning any medium supplemented with any concentration and/or combination of growth factors and serum would result in the induction of differentiation of IPE to myocardial cells. Undue experimentation would be required of a skilled artisan to determine the specific differentiation inducing condition for obtaining the claimed directed differentiation of IPE cells to myocardial cells.

14. It is well-known in the art that endogenous and exogenous factors govern the expansion, maintenance and differentiation of stem cells in vitro, a prime one being the cultivation condition. For example, Reynolds et al. (Sc. 255: 1707-1710, 1992; page 1707, col 2, para 1) teach that cell division and proliferation to form spheres was only achieved with EGF, however, was not mimicked by NGF or bFGF. Mokry et al teach that in case of adherent cultures of neural stem cells, various factors affect cell differentiation and the ratio of the resulting cell types. Modifications in culture conditions influencing cell differentiation include medium constituents like serum, growth factors, hormones, differentiation factors, etc. Mokry et al provide a cautionary note stating that "a change in cultivation condition resulted in cell death that reduced the numbers of cells that differentiated" (Acta Med 50: 35-41, 2007; page 39, para 2). However, the relevant literature, does not teach that iris pigment epithelial cells can be induced to differentiate into myocardial cells by culturing the IPE cells under any culture condition as broadly claimed. The skilled artisan will not be able to make and use the claimed invention, thereby entail innumerable trials and errors leading to undue experimentation.

Please note that this rejection can be overcome by elaborating on the "differentiation inducing conditions" of step (v), claim 1, for example reciting a specific medium and other essential constituents required for performing the claimed method of inducing differentiaion of IPE to myocardial cells in the independent claim.

15. Due to the large quantity of experimentation necessary for inducing differentiation of IPE cells to myocardial cells using any differentiation inducing condition, comprising any medium, growth factor and serum at any concentration; the lack of direction/guidance presented in the specification; the complex nature of the invention; the unpredictability of reproducible differentiation of stem cells precipitated by changes in the cultivation conditions or medium constituents; undue experimentation would be required of the skilled artisan to make and/or use the claimed invention.

Claim Rejections - 35 USC § 112-Written Description

16. Claims 1-4, 6, 8-11, 17-18 and 26-27, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

17. The claims are drawn to a method for producing myocardial tissue cells comprising: (i) obtaining iris pigment epithelial cells and dissociating the isolated cells; (ii) culturing epithelial cells by floated coagulated mass in serum free media with N2 supplement and obtaining pluripotent stem cells (claim 1-3); (iii) wherein the stem cells are Oct-3/4 positive (claim 4); (iv) culturing the cells in avian or

fetal calf serum containing media, wherein the medium contains a growth factor (e.g. FGF, EGF, etc.) (claims 8-11). The claims further recite the extirpation of iris tissue by excising the tissue from the eyeball of an animal, treating with enzyme (dispase and EDTA) and restoring the tissue in medium containing fetal calf serum (claim 6, 26-27). Furthermore, the claims recite testing for a myocardial cell specific gene, for example myosin (claims 17, 18).

18. The specification of the instant application teaches that the iris pigment epithelial cells are obtained from the eyeball of a chick, followed by selective culturing of the cells using the (neurosphere) method of floated coagulated mass culture in a serum-free culture medium (DMEM/F12, N2 supplement and growth factors FGF2, LIF or SCF) (Example1, pages 18-20). The specification further teaches the differentiation of the iris derived cells under various differentiation inducing culture conditions, and suggests, that the cells can differentiate into all types of tridermic tissues (Example 2, page 21, para 2). The specification generically defines “culturing under the differentiation inducing condition” as “culturing under any publicly known conventional condition designed to differentiate cells", such as culturing using a medium (e.g. DMEM, DMEM/F12) to which serum (e.g. fetal calf serum or avian serum) and growth factor (e.g. FGF, EGF) are added, thereby inducing differentiation to cells (page 5, para 2; Example 1, pages 18-20). Example 2 of the instant specification teaches that stem cells cultured for two months in DMEM comprising specific concentrations of EGF, FGF2, fetal calf serum and avian serum (page 20, para 1, condition 3)

resulted in the expression of genes specific for myocardial cells, such as GATA4, Nkx2.5, myosin, etc. (Example 2, pages 20-22; Figure 4). However, the brief description in the specification of one example of differentiation inducing condition (DMEM, EGF, FGF2, fetal calf serum and avian serum), and one example of serum free culture medium (DMEM/F12 with N2 supplement) does not provide adequate written description of an entire genus of conditions inducing a targeted differentiation of IPE cells to myocardial cells expressing myocardial genes, or an entire genus of serum-free culture medium. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of specific physiological characteristics, physical and/or chemical properties, functional features, structure/function correlation, or any combination thereof. However, in this case, the specification has not shown a relationship between the claimed genus of differentiation inducing conditions required for differentiation to myocardial cells, and between the claimed genus of serum-free culture media required for the floated coagulated mass culture method.

19. *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed"* (See page 1117). The specification does not "clearly allow persons of ordinary skill in the

art to recognize that [he or she] invented what is claimed" (See *Vas-Cath* at page 1116).

20. The skilled artisan cannot envision the entire genus of differentiation inducing conditions and the serum-free culture media of the encompassed methods, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

21. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class.

22. Therefore, only methods comprising differentiation inducing conditions comprising DMEM, EMEM, growth factors like EGF, FGF2, serum like fetal calf serum and avian serum, and serum-free culture media of DMEM/F12 with N2 supplement, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

23. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

24. Claims 1-4, 6, 8-11, 17-18 and 26-27, are rejected under 35 U.S.C. 103(a) as being unpatentable over Kosaka et al. (Exp Cell Res 245: 245-251, 1998), in view of Tropepe et al. (Sc. 287: 2032-2036, 2000), and further in view of Pardo et al. (Brain Res 818: 84-95, 1999), as evidenced by Reynolds et al. (Sc. 255: 1707-1710, 1992).

25. The claims are drawn to a method for producing myocardial tissue cells comprising: (i) obtaining iris pigment epithelial cells and dissociating the isolated cells; (ii) culturing epithelial cells by floated coagulated mass in serum free media

with N2 supplement and obtaining pluripotent stem cells (claim 1-3); (iii) wherein the stem cells are Oct-3/4 positive (claim 4); (iv) culturing the cells in avian or fetal calf serum containing media, wherein the medium contains a growth factor (e.g. FGF, EGF, etc.) (claims 8-11). The claims further recite the extirpation of iris tissue by excising the tissue from the eyeball of an animal, treating with enzyme (dispase and EDTA) and restoring the tissue in medium containing fetal calf serum (claim 6, 26-27). Furthermore, the claims recite testing for a myocardial cell specific gene, for example myosin (claims 17, 18).

26. Kosaka et al. teach the removal of eyeballs from 1 day old (postnatal) chicken, followed by incision around the iris, incubating the tissue in dispase solution and thereafter in EDTA (page 246, col 1, para 3), mechanically isolating the pigmented epithelial cells from the iris so as to prevent contamination with the other cell types, and culture in Eagle's MEM (EMEM) medium containing fetal bovine serum. Isolated pigmented epithelia are thereafter dissociated into a single cell suspension after treatment with 0.1% trypsin in PBS (page 246, column 1, "Preparation of cell"). Kosaka et al. further teach the growth of the iris derived pigmented epithelial cells in culture for 18 days before reaching confluency. The depigmented iris pigment epithelial cells are harvested and cultured for transdifferentiation to lens tissue using EMEM medium with serum and FGF (page 246, column 1, "Procedure for cell culture"; page 248, col 1, para 2).

27. Kosaka et al. do not teach the culturing of iris pigment epithelium cells by

a floated coagulated mass culturing technique.

28. Tropepe et al. teach the proliferation of pigmented cells from the ciliary margin (PCM) obtained from adult mouse eyes using the in vitro spherical colony forming culture method. Specifically, Tropepe et al. teach the formation of free-floating PCM spheres using the "neurosphere" formation culture method of Reynolds et al (see cross-reference 6, 8; page 2032, col 2) comprising culturing in serum-free culture medium supplemented with a defined hormone and salt mixture (comprising insulin, transferrin, progesterone, putrescine and selenium salt). Although the reference does not mention N2 supplement, the ingredients of the salt mixture presented in parenthesis above correspond to N2 supplement (see N2 Product Description Sheet from Stem Cell technologies). Furthermore, Tropepe et al teach that the coagulated mass culture results in PCM stem cells that are multipotential (page 2034, col 1, para 2).

29. Kosaka et al. and Tropepe et al. do not teach rotation of the IPE cells in culture medium during the floated coagulated mass culturing technique.

30. Pardo et al. teach aggregating brain cell cultures as an useful in vitro model for brain ischemia. The reference teaches that cell aggregates in culture can be mediated by rotation to form even-sized spherical structures comprising neuronal cells (abstract, Introduction), similar to coagulated cell mass of the instant claims.

31. Kosaka et al., Tropepe et al., and Pardo et al, do not explicitly

teach the expression of Oct3/4. However, this limitation is not intended as part of the claimed method, rather is intended to recite a characteristic of the claimed pluripotent stem cells. Additionally, since the cells of Kosaka et al. are derived from the same source as the instant application, are cultured under similar differentiation conditions, and use the floated coagulated mass culture of Tropepe et al. producing multipotential cells, the teachings of the combined references as explained above inherently describe cells having the same differentiation properties, and express similar marker, absent evidence to the contrary. That the references are silent on the expression of the cardiac marker genes does not provide proof of the cell being different, particularly if the other conditions (as stated above) are satisfied.

32. It would have been, therefore, obvious to the person of ordinary skill in the art at the time the claimed invention was made to modify the method of culturing the iris pigment epithelial cells of Kosaka et al. with rotation as taught by Pardo et al., to the floated coagulated mass culture technique as taught by Tropepe et al. The person of ordinary skill in the art would have been motivated to use the floated coagulated mass culture technique for cell culture and differentiation as this would produce multipotent (or pluripotent) cells demonstrating various lineages (Tropepe et al., page 2034, col 1, para 2). Furthermore, as evidenced by Reynolds et al., the method would facilitate the selection of a specific cell type aggregate by antibody immuno-staining (page 708, Figure 1E and 1F). The person of ordinary skill in the art would have expected success because the

method of floated coagulated mass technique involving various tissues, was well established and accepted in the art at the time the invention was made.

33. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

Applicant's Response

34. Applicant's arguments directed to the 103 rejection (over the combined references of Kosaka et al., Haruta et al. and Reynolds et al.) of the previous Office Action, are considered moot as the rejection has been withdrawn (see para 5 of the instant action). However, Applicant's general comments on the claimed technique, asserting that the "culturing of the obtained stem cells under differentiation inducing condition of the instantly claimed invention attains an unexpected effect such that myocardial cells are obtained from the stem cells", will be addressed below.

35. Applicant asserts that the floated coagulated mass culturing technique initiates from a relatively low number of IPE cells, that results in "unpigmenting" the IPE cells to produce pluripotent stem cells by selective culturing. Applicant further asserts that the culture conditions produce the unexpected effect of obtaining myocardial cells. Applicant provides references (one of the authors being the instant Inventor) to demonstrate that the pluripotent cells obtained by the instant method can differentiate to various tissues.

36. Applicant's arguments and the references are fully considered, however, are not found to be persuasive. Firstly, Applicant's explanation of the culture conditions, emphasizing on the low density culturing method is not a part of the instant claims. Arguments that rely on particular distinguishing features are not persuasive when those features are not recited in the claims. Additionally, it is to be noted that Tropepe et al. teach that PCM sphere colonies were obtained by the proliferation of a single PCM cell in low-density cultures (page 2033, col 2, para 1). The combination of the above references proves that the knowledge and expertise for the claimed method for selective culturing and differentiating pluripotent stem cells to various lineages was known in the art and the results were expected to be successful. The prima facie obviousness of the claimed invention in view of the combined references, therefore, provides sufficient reasoning. Applicant's assertion of unexpected results is inappropriate, because of obvious expected properties taught in the prior art, either explicitly or implicitly. "Where the unexpected properties of a claimed invention are not shown to have a significance equal to or greater than the expected properties, the evidence of unexpected properties may not be sufficient to rebut the evidence of obviousness". *In re Nolan*, 553 F.2d 1261, 1267, 193 USPQ 641, 645 (CCPA 1977).

Conclusion

37. No claim is allowed

38. The prior art Kosaka, M (Proc of the 36th Meet of the Jap Soc Dev Biologists, received by JST on 6/10/2003), vol 36, page 38 (SII-3), is made of record, but not relied upon for rejection, because the only date on the reference – 6/10/2003:

(a) Does not qualify for a 102(b) rejection based upon the date – 6/10/2004 for the PCT/JP04/08120, of which the instant application is a national stage application (i.e. the reference date is exactly one year but not more than a year).

(b) Does not qualify for a 102(a), 102(e) or 103(a), because the reference is not by another, i.e. has the same inventive entity.

39. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aditi Dutt whose telephone number is (571) 272-9037. The examiner can normally be reached on Monday through Friday, 9:00 a.m. to 5:00 p.m.

40. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker, can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

41. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through

Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov/. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AD
26 January 2008

/Jeffrey Stucker/

Supervisory Patent Examiner, Art Unit 1649